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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,086

08/17/2006

Hiroshi Kawazoe

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02/04/2010

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

02/04/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,086	<b>Applicant(s)</b> KAWAZOE ET AL.	
	<b>Examiner</b> Jan M. Ludlow	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/19/2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- I. Claims 1-17, including an exposed fiber;
- II. Claim 18, including a terminal connection;
- III. Claim 19, including an non-porous fiber.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

1. The claims are deemed to correspond to the species listed above in the following manner:

- I. Claims 1-17, including an exposed fiber;
- II. Claim 18, including a terminal connection;
- III. Claim 19, including an non-porous fiber.

The following claim(s) are generic: none.

2. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

3. The claims have in common the "special technical feature" of a first plate, a hollow fiber with an internal region having a function. This does not constitute a "special technical feature" because such features are taught by Durst, as described below.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
5. Newly submitted claims 18-19 are directed to an invention that is independent or distinct from the invention originally claimed for the above reasons.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**1. Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

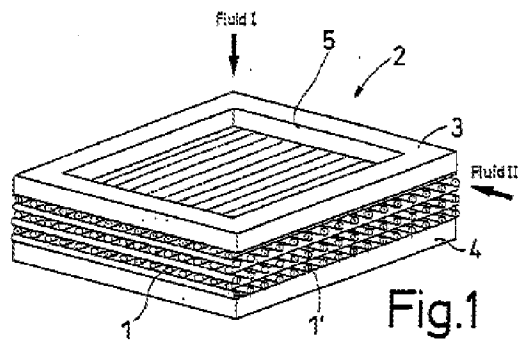
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 12-13 and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Durst et al. (DE 4308697).
3. With respect to claim 1, Durst et al. teaches a upper frame part (3, fig. 1) (first supporting plate) and a least one capillary hollow fiber (1) (hollow filament) constituting

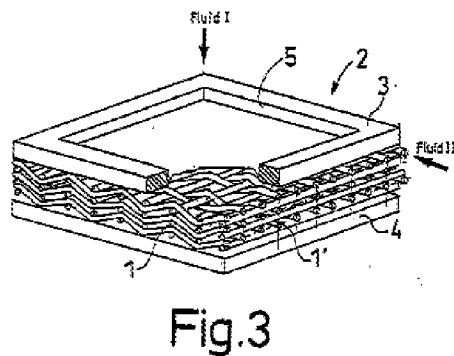
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the channel of the microfluid system, wherein the capillary hollow fiber (1) (hollow filament) is placed on the upper frame part (3) (first supporting plate) in any shape, and a particular internal region of the capillary hollow fiber (1) (hollow filament) has a function (page 1, lines 7-11; fig. 1).



4. With respect to claim 2, Durst et al. teaches more than one capillary hollow fiber (1) (hollow filament) are placed (fig. 1).

5. With respect to claim 3, Durst et al. teaches at least one capillary hollow fiber (1) (hollow filament) in any shape having no function in the internal particular region is placed additionally on the upper frame part (3) (first supporting plate) (fig. 1, fig. 3).



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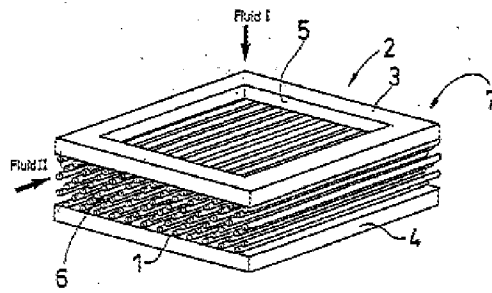
6. With respect to claims 4 and 5, Durst et al. teaches at least one capillary hollow fiber (1) (hollow filament) is placed crosswise to at least another capillary hollow fiber (1) (hollow filament; placed crosswise the capillary hollow fiber (1) (hollow filament) itself (fig. 1, fig. 3).

7. With respect to claim 6, Durst et al. teaches a lower frame part (4) (second supporting plate), wherein at least one capillary hollow fiber (1) (hollow filament) is held between the upper and lower frame part (3, 4) (first and second supporting plates) (fig. 1).

8. With respect to claim 7, Durst et al. teaches part of at least one capillary hollow fiber (1) (hollow filament) is exposed through at least one of the upper and lower frame part (3, 4)(first and second supporting plates) (fig. 1).

9. With respect to claims 8, Durst et al. teaches at least one hollow filament has a inlet and discharge openings (port) for at least one of receiving a fluid from outside and discharging it to the outside (page 14, lines 10-23).

10. With respect to claim 9, Durst et al. teaches the inlet and discharge opening (5) (port) is fixed to (at least one of) the upper frame part (first and second supporting plates) (fig. 4).



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11. With respect to claim 12, Durst et al. teaches the membrane modules are covered by a cylindrical housing light (light transmitting property) the capillary hollow fibers penetrate the housing. It appears the capillary hollow fibers of Durst et al. would meet this limitation (10, lines 20-29).

12. With respect to claim 13, Durst et al. teaches the function of the capillary hollow fiber (1) (hollow filament) is a function selected from a group consisting of separation (adsorption-desorption, ion exchange, removal, partition and oxidation-reduction) (page 1, lines 7-11).

13. With respect to claims 17, Durst et al. teaches at least one hollow filament has a inlet and discharge openings (port) for at least one of receiving a fluid from outside and discharging it to the outside (page 14, lines 10-23).

#### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durst et al. (DE 4308697) in view of Wolk (US 6,148,508).

17. With respect to claim 10, modified Durst et al. does not specifically teach a relay unit for connecting the hollow filaments to each other. However, it appears the capillary hollow fibers of Durst et al. are connected to each other, which would meet this limitation (fig. 1, fig. 3). Wolk teaches a capillary element (438, fig. 4B) (relay unit) for connecting the capillary channels (440) (hollow filaments) to each other. It would have been obvious to one of ordinary skill in the art that the insertion of the capillary element into the opening places the capillary channel into fluid communication with at least one of the channels in the integrated channel network within the body structure (col. 6, lines 3-7) as taught by Wolk. The capillary element (relay unit) of Wolk, has a channel disposed through it, which connects it to a channel network (hollow filaments) (col. 2, lines 36-43).



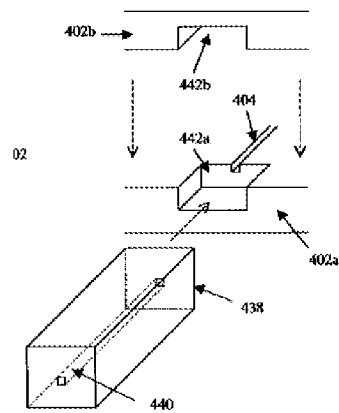


Figure 4B

18. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durst et al. (DE 4308697) in view of Frazier et al. (US 7,048,723).

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19. With respect to claim 11, Durst et al. does not specifically teach a metal layer is formed on a particular region of at least one hollow filament. Frazier et al. teaches a coating such as gold (metal layer) is formed on a particular region of at least on microneedle (hollow filament) (col. 4, lines 44-52; col.7, lines 9-12). It would have been obvious to one of ordinary skill in the art to modify the device of Durst et al. to provide a gold layer on a region of the hollow filament given the teaching of Frazier et al. in order to passage of an electric current via flash electroplating (col. 7, lines 9-24) as taught by Frazier et al.

20. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durst et al. (DE 4308697) in view of Anderson et al. (US 2002/0015952).

21. With respect to claims 14 and 16, Durst et al. does not specifically teach fixing a filler in a particular internal region of at least one hollow filament; the function is provided by forming a porous material in a particular internal region of at least one hollow filament. Anderson et al. teaches the function is provided by beads are packed (fixing a filler in a particular internal region) in the hollow fiber (hollow filament) (par. 0174, lines 1-3; lines 7-8). Anderson et al. further describes the beads as being made from silica or gel beads and porous polystyrene (par. 0058, lines 5-10). It would have been obvious to one of ordinary skill in the art to modify the device of Durst et al. to fix beads (filler) in a particular internal region of the hollow filament (par. 0174, lines 4-5) as taught by Anderson et al. in order to adhere different fibers together (par. 0174, lines 3-4).

22. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durst et al. (DE 4308697) in view of Kitaguchi et al. (US 6,148,508).

23. With respect to claim 15, Durst et al. does not specifically teach graft polymerization on a particular internal region of at least one hollow filament. Kitaguchi et al. teaches function is provided by graft polymerization on the inner surface of the capillary (a particular internal region of at least one hollow filament) (par. 0250, lines 8-11). It would have been obvious to one of ordinary skill in the art to use graft

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polymerization to produce stable electroosmosis flows (par. 0250, lines 6-9) as taught by Kitaguchi et al.

### ***Double Patenting***

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24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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25. Claims 1-11 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8 of copending Application No. 10/505,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a microfluid system comprising a first supporting plate, at least one hollow filament. The limitations of claims 1-11 are encompassed within the claims of 10/505,416.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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The reference Nichols (US 4, 959, 152) teaches a hollow fiber separation module and method for the use thereof.

The reference Hoopman et al. (US 5, 070, 606) teaches a method for producing a sheet member containing at least one enclosed channel.

The reference Sarrut et al. (FR 2813073) teaches Device for biological, chemical pharmaceutical and medical uses, comprises channels and a reception area for guiding and positioning capillaries to connect to a micro-fluidic component.

The reference Kawazoe et al. (US 10/505,416) teaches micro fluid system support and manufacturing method thereof.

The reference Tzeng et al. (TW 536524B) teaches a network-type microchannel device for micro-fluid.

1. Applicant's arguments filed October 19, 2009 have been fully considered but they are not persuasive.

Applicant argues that Durst teaches "not that Fluid II is admitted into the hollow capillary as is claimed in the present invention." This argument is not persuasive because the instant claims are apparatus claims, not method claims. There is no instant claim limitation to the method step of, e.g., "admitting fluid into the hollow capillary," nor would it be clear what structural limitation would be intended if such a *method* step limitation were presented in the instant *apparatus* claims. Further, the Figures do show Fluid II inserted in the capillaries, and Fluid I flowing over the capillaries for mass exchange through the pores. With respect to "a function," Durst teaches the use of the polysulfone fibers of Ly (4970034). Polysulfone is inherently hydrophobic (a function), and the fibers of Ly can be treated to be more hydrophilic, less adsorptive and more biocompatible (all functions) [Ly, col. 3, lines 37-51]. Part of the fiber is exposed through the central opening in plate 3 as shown by the parallel lines of the fibers shown in, e.g., figures 1 and 4.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday, Tuesday and Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner  
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